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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,129	05/09/2006	Rolf Berge	CU-4424 RJS	1333
26530 LADAS & PAR	7590 12/22/201 RRY LLP	0	EXAMINER	
224 SOUTH MICHIGAN AVENUE			SCHLIENTZ, NATHAN W	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/550,129	BERGE, ROLF				
Office Action Summary	Examiner	Art Unit				
	Nathan W. Schlientz	1616				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 26 Fe	ebruary 2010.					
	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
- 4)⊠ Claim(s) <u>48-108</u> is/are pending in the application.						
4a) Of the above claim(s) <u>49-55,57,59-63,65,67,68,70,72 and 74-108</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) <u>48,56,58,64,66,69,71 and 73</u> is/are re	jected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10)⊠ The drawing(s) filed on 21 September 2005 is/a	ure: a)⊠ accepted or b)□ objec	ted to by the Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☒ None of:						
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	_					
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal P					
Paper No(s)/Mail Date <u>7/20/06</u> . 6) Other:						

### **DETAILED ACTION**

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#### Election/Restrictions

Applicant's election with traverse of the invention of Group I and the species metabolic syndrome and tetradecylthioacetic acid (TTA) in the replies filed on 26 February 2010 and 07 December 2010 is acknowledged. The traversal is on the ground(s) that the phospholipids of U.S. 4,849,019 are "normal" phospholipids and do not contain a non-β-oxidizable fatty acid entity. The single inventive concept is thus this unique combination of a plant or fish oil and a non-β-oxidizable lipid, and this single concept unifies the aspects indicated as Group I, II, and III. This is not found persuasive because US 6,365,628 discloses administering high sucrose + TTA diets and high fat + TTA diets to rats, wherein the high sucrose and high fat diets comprise sunflower oil (col. 7, In. 16-42). US '628 further discloses the treatment of the metabolic syndrome with their compositions (col. 3, In. 41-52; and Examples 11-19).

The requirement is still deemed proper and is therefore made FINAL.

#### Status of the Claims

Claims 48-108 are pending in the present application. Applicant's elected the invention of Group I, claims 48-84, and the species metabolic syndrome and tetradecylthioacetic acid. Therefore, claims 85-108 are withdrawn as being drawn to a nonelected invention, and claims 49-55, 57, 59-63, 65, 67, 68, 70, 72 and 74-84 are withdrawn as being drawn to a nonelected species. Thus, claims 48, 56, 58, 64, 66, 69,

71 and 73 are examined herein on the merits for patentability. No claims are allowed at this time.

### Claim Objections

1. Claim 48 is objected to because of the following informalities: the letter "O" is replaced by the number "0" in the formulas for serine, ethanolamine, choline, glycerol and inositol. Appropriate correction is required.

### Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) treatment of the metabolic syndrome and (2) tetradecylthioacetic acid or salts thereof, does not reasonably provide enablement for (1) *prevention* of the recited diseases/disorders, and (2) *prodrugs* of the non-β-oxidizable fatty acid entities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure

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would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention

2) the state of the prior art

3) the relative skill of those in the art

4) the predictability of the art

5) the breadth of the claims

6) the amount of direction or guidance provided

7) the presence or absence of working examples

8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

#### The nature of the invention

The claimed invention relates to a method of prevention and/or treatment of the metabolic syndrome comprising administering a plant and/or fish oil and tetradecylthioacetic acid.

### The state of the prior art

It was known in the art at the time of filing the instant invention that supplementing the diet with plant and/or fish oil will help treat the metabolic syndrome. It was also known that administering TTA will treat the metabolic syndrome.

### The predictability of the art

As discussed by Testa in Biochemical Pharmacology, 2004, on page 2098, right column, a number of challenges await medicinal chemists and biochemists carrying out prodrug research, such as the additional work involved in synthesis, physicochemical profiling, pharmacokinetic profiling and toxicological assessment. Two of these

challenges are introduced here, namely biological variability and toxicity potential. The challenge of biological variety results principally but not only from the huge number and evolutionary diversity of enzymes involved in xenobiotic metabolism. Inter- and intraspecies differences in the nature of these enzymes, as well as many other differences such as the nature and level of transporters, may render prodrug optimization difficult to predict and achieve. The high levels of carboxylesterases in the plasma of rodents but not of other mammals is but one example of a biological difference that may affect the rate and site of activation of some prodrug esters, as seen for example with the ACE inhibitor benazepril.

#### The breadth of the claims

The instant claims are drawn to a method of prevention and/or treatment of the metabolic syndrome comprising administering a plant and/or fish oil and tetradecylthioacetic acid or a salt or prodrug thereof. "Prevention" is defined in Webster's New World Dictionary as "to keep from happening; make impossible by prior action." Thus, prevention is regarded as 100% effective. Therefore, 100% of patients administered a plant and/or fish oil and tetradecylthioacetic acid would never acquire the metabolic syndrome. Prodrugs are chemicals with little or no pharmacological activity, undergoing biotransformation to a therapeutically active metabolite (TTA).

### The amount of direction or guidance provided

The instant specification states that the term "prevention" refers to the preventing of a given disease, i.e. a compound of the present invention is administered prior to the onset of the condition. This means that the compounds of the present invention can be

used as prophylactic agents or as ingredients in a nutritional composition in order to prevent the risk or onset of a given disease. The specification does not provide any guidance with regard to determining what compounds would constitute a prodrug of TTA.

### The presence or absence of working examples

The instant specification does not provide examples wherein administering fish and/or plant oil and TTA resulting in 100% prevention of the metabolic syndrome. The specification also does not provide any examples of prodrugs of TTA.

## The quantity of experimentation necessary

It would require undue experimentation to determine if administering plant and/or fish oil with TTA would result in 100% prevention in all patients. Also, it would require undue experimentation to determine what compounds would constitute a prodrug of TTA.

Therefore, for the aforementioned reasons, the Applicant is enabled for (1) treatment of the metabolic syndrome and (2) tetradecylthioacetic acid or salts thereof, but is not reasonably enabled for (1) *prevention* of the recited diseases/disorders, and (2) *prodrugs* of the non β-oxidizable fatty acid entities.

## Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 recites, "non  $\beta$ -oxidizable fatty acid entities represented by (a) the general formula R"-COO-(CH<sub>2</sub>)<sub>2n+1</sub>-X-R'..." However, it is noted that the formula R"-COO-(CH<sub>2</sub>)<sub>2n+1</sub>-X-R' (depicted below) does not represent fatty acid entities. It is believed that applicant intended to state R"-OCO-(CH<sub>2</sub>)<sub>2n+1</sub>-X-R' or R'-X-(CH<sub>2</sub>)<sub>2n+1</sub>-COO-R" (depicted below).

Applicant is reminded that any change to the claims and or specification must find support in the originally filed application so as not to introduce new matter.

4. Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 48 recites, "one or more heterogroups selected from the group comprising... a CH<sub>2</sub> group". First, the recitation of "selected from the group *comprising*" is not a proper Markush limitation. See MPEP 803.02. Second, a CH<sub>2</sub> group is not considered a heterogroup because it does not comprise any heteroatoms. Claims 58 and 59 also recite "selected from the group *comprising*", which is an improper Markush limitation.

5. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 64 recites the broad recitation "about 1-200 mg/kg", and the claim also recites "preferably 5-50 mg/kg for human consumption" which is the narrower statement of the range/limitation. The claim also recites the broad recitation "about 1-2000 mg/kg", and the claim also recites "preferably 5-500 mg/kg, for animal consumption" which is the narrower statement of the range/limitation. Also, the genus "animal" encompasses Therefore, the claim states that the dosage for animals, which includes humans. humans, is broader than the dosage recited for humans.

6. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 66 recites the broad recitation "about 1-300 mg/kg", and the claim also recites "preferably 10-150 mg/kg for human consumption" which is the narrower statement of the range/limitation. Also, the genus "animal" encompasses humans. Therefore, the claim states that the dosage for animals, which includes humans, is broader (from 1 mg/kg up to the total daily fat consumption) than the dosage recited for humans.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Berge (US 6,365,628).

Berge discloses that the compounds of the present invention, preferably TTA, have been shown to provide a positive effect on hyperinsulinemia, insulin resistance, obesity, glucose intolerance, Type 2 diabetes mellitus, dyslipidemia and hypertension, i.e. by regulating both the glucose and lipid homeostasis, and thus it is anticipated that the compounds of the present invention will be suitable agents for the regulation of the metabolic disease (sometimes called syndrome X or the metabolic syndrome) (col. 3, In.

41-52). Berge further discloses that a further aspect of the invention relates to the use a compound of the formula I, preferably TTA, for the preparation of a pharmaceutical composition for the treatment and/or prevention of the multi metabolic syndrome termed </metabolic syndrome>> which is inter alia characterized by hyperinsulinemia, insulin resistance, obesity, glucose intolerance, Type 2 diabetes mellitus, dyslipidemia and/or hypertension (col. 4, In. 28-39).

Berge disclose oral administration of TTA at dose levels up to 500 mg/kg/day was generally well tolerated. The dose level of 500 mg/kg/day also elicited body weight loss. There was no evidence of toxicity at dose levels of 50 or 500 mg/day/kg (Example 2).

Berge also discloses administering high sucrose + TTA (0.3%) diets and high fat + TTA (0.4%) diets to rats, wherein the high sucrose and high fat diets comprise sunflower oil (1% and 7.1%, respectively) (col. 7, ln. 16-42). Rats fed the high sucrose +TTA and high fat + TTA diets experienced weight loss, prevention of increase in adipose tissue mass, prevention in high fat diet-induced hyperinsulinemia, and prevention in high fat diet-induced insulin resistance (Examples 5-19; and Figures 1-7). Therefore, Berge discloses administering a diet comprising TTA and sunflower oil to rats, wherein the metabolic syndrome is treated.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claims 48, 56, 58, 64, 66, 69, 71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berge et al. (Current Opinion in Lipidology, 2002), Madsen et al. (Journal of Lipid Research, 2002), and Skorve et al. (Biochimie, 2005) in view of Aude et al. (Current Opinion in Cardiology, 2004), Storlien et al. (Science, 1987), Esposito et al. (Journal of the American Medical Association, 2004) and Aguilera et al. (Journal of Nutritional Biochemistry, 2004).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Berge et al. teach that the biological responses of TTA include mitochondrial proliferation, increased catabolism of fatty acids, antiadiposity, improvement in insulin sensitivity, antioxidant properties, reduced proliferation and induction of apoptosis in rapidly proliferating cells, cell differentiation and anti-inflammatory action. These biological responses indicate that TTA changes the plasma profile from atherogenic to cardioprotective. TTA regulates the adipose tissue mass and the expression of lipid

metabolizing enzymes (Abstract). Berge et al. further teach that it has been found that structurally modified fatty acids show an enhanced potency in modulating critical steps in lipid metabolism compared with many of the biologically formed compounds. Such modified fatty acids have the potential to be beneficial to general health both as therapeutic and as disease preventive agents, *alone and in combination with other bioactive lipids*. One such modified fatty acid is the sulfur-containing TTA, which has been found to beneficially affect disorders in lipid metabolism (pg. 295, right column,  $2^{nd}$  paragraph). Berge et al. further teach that TTA and eicosapentaenoic acid (EPA) reduce the plasma triacylglycerol level by increasing the number of mitochondria and by stimulating the mitochondrial  $\beta$ -oxidation of normal fatty acids to ketone bodies. These data unequivocally demonstrate that the hypotriacylglycerolidemic action of EPA, TTA and fenofibrate is linked to increased mitochondrial  $\beta$ -oxidation and can be dissociated from peroxisome proliferation (pg. 296, right column, last paragraph).

Madsen et al. teach that TTA has the ability to prevent diet-induced and genetically determined adiposity and insulin resistance. In rats fed a high fat diet, TTA administration completely prevented diet-induced insulin resistance and adiposity. In genetically obese rats, TTA treatment reduced the epididymal adipose tissue mass and improved insulin sensitivity. The results suggest that a TTA-induced increase in hepatic fatty acid oxidation and ketogenesis drains fatty acids from blood and extrahepatic tissues and that this contributes significantly to the beneficial effects of TTA on fat mass accumulation and peripheral insulin sensitivity (Abstract). Madsen et al. further teach that insulin resistance with ensuing hyperinsulinemia and dyslipidemia characterizes the

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metabolic syndrome (pg. 742, left column, last paragraph). Also, feeding TTA to rats causes a significant reduction of plasma triacylglycerol accompanied by increased mitochondrial and peroxisomal  $\beta$ -oxidation in the liver (pg. 742, right column,  $2^{nd}$  paragraph). Madsen et al. teach that TTA prevents high fat diet-induced increase in adipose tissue mass, high fat diet-induced hyperinsulinemia, high fat diet-induced insulin resistance *in vivo*, decreases plasma triacylglycerol levels and activates PPAR $\alpha$ -dependent pathways *in vivo*, and activates PPAR subtypes (pg. 744-748).

Skorve et al. teach that TTA has beneficial effects on lipid transport and utilization, and can be used to treat the metabolic syndrome (Abstract; pg. 15-19). Skorve et al. further teach that high intake of fish seems to promote a reduced risk of cardiovascular diseases, and marine polyunsaturated fatty acids have a striking cholesterol-lowering effect (pg. 16, left column, 2<sup>nd</sup> full paragraph). Skorve et al. teach that mitochondria rather than peroxisomes are the important organelles in regulating plasma triglyceride levels after TTA and fish oil feeding. TTA and EPA reduce plasma triglyceride levels by increasing the number of mitochondria and by stimulating the mitochondrial β-oxidation of normal fatty acids to ketone bodies. The data unequivocally demonstrate that the hypotriglyceridaemic action of EPA and TTA is linked to increased mitochondrial β-oxidation, and can be dissociated from peroxisome proliferation (pg. 18, left column, 2<sup>nd</sup> paragraph).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Berge et al., Madsen et al. and Skorve et al. do not explicitly disclose combining TTA with fish oil and/or plant oil in the treatment of the metabolic syndrome, as instantly claimed.

Aude et al. teach that clinical trials and epidemiologic studies have shown that both marine- and plant-derived omega-3 fatty acids reduce the incidence of coronary heart disease (CHD). Several prospective clinical studies for secondary prevention suggest that EPA and DHA supplementation, as fatty fish or dietary supplements, significantly reduce cardiac and all-cause mortality. The omega-3 fatty acids from fish and fish oil can significantly reduce plasma triglycerides. The triglyceride-lowering effect of the omega-3 fatty acids is dose related and is comparable in both diabetics and nondiabetics. Also, α-linolenic acid-derived omega-3 fatty acids are beneficial in secondary prevention of CHD, wherein the major food source of α-linolenic acid are vegetable oils (mostly canola and soybean oils) (pg. 475, right column, Fish, fish oil, and omega-3 fatty acids). Aude et al. further teach that patients who had experienced their first myocardial infarction and adopted a Mediterranean-style diet (enriched with αlinolenic acid), experienced an impressive reduction in cardiovascular events and mortality, without a significant change in body weight or lipid levels (pg. 477, left column, 1<sup>st</sup> full paragraph).

Storlien et al. teach that a major metabolic abnormality of non-insulin-dependent diabetes is impaired insulin action (insulin resistance). Diets high in fat from vegetable and nonaquatic animal sources (rich in linoleic acid, an omega-6 fatty acid, and saturated fats) lead to insulin resistance. In rats fed high-fat diets, replacement of only

6 percent of the linoleic omega-6 fatty acids from safflower oil with long-chain polyunsaturated omega-3 fatty acids from fish oil prevented the development of insulin resistance. The effect was most pronounced in the liver and skeletal muscle, which have important roles in glucose supply and demand. The results may be important for therapy or prevention of non-insulin-dependent diabetes mellitus (Abstract).

Esposito et al. teach that a Mediterranean-style diet rich in whole grains, fruits, vegetables, legumes, walnuts, and olive oil might be effective in reducing both the prevalence of the metabolic syndrome and its associated cardiovascular risk (pg. 1446, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph).

Aguilera et al. teach that dietary fish oil in (n-3) fatty acids play an important role in reducing abnormalities associated with the metabolic syndrome (Abstract).

### Finding of prima facie obviousness

# Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to combine TTA and fish and/or vegetable oil in the treatment of the metabolic syndrome. Such would have been obvious in the absence of evidence to the contrary because it is generally *prima facie* obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. *In re Kerkhoven* 626 F.2d 646, 850, 205 USPQ 1069, 1072 (CCPA 1980).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**NWS** 

/John Pak/ Primary Examiner, Art Unit 1616